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PATENT
Attorney Docket No. 469443-00004/67279-5/RFT/RMS/RMK

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

David A. Horwitz

Serial No. 10028,944

Filed: December 21, 2001

For: *Use of Cytokines and Mitogens to Inhibit Pathological Immune Responses*

Examiner. To be assigned

Group Art Unit: 1651

CERTIFICATE OF MAILING
I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: BOX MISSING PARTS/FEE, Assistant Commissioner for Patents, Washington, D.C. 20231 on:
Date: August 2, 2002
Signature Mary McFarland
Mary McFarland

Preliminary Amendment

BOX MISSING PARTS/FEE
Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Prior to examination please amend the above-identified application as follows:

In the Specification

On page 1, line 3, please add the following new paragraph:

--This application is a continuing application of United States Serial No. 09/564,436, filed May 4, 20000, now U.S. Patent No. 6,358,506, which is a continuing application of 09/187,771, filed November 5, 1998, now U.S. Patent No. 6,228,359, and claims the benefit of the filing dates of United States Serial No. 60/132,616, filed May 5, 1999 and 60/064,507, filed November 5, 1997.—

In the Claims

Please cancel claim 1.

Please add the following new claims:

--24. A method for treating an autoimmune disorder in a patient comprising:

a) removing peripheral blood mononuclear cells (PBMC) from said patient;

b) treating said cells with a regulatory composition to generate regulatory T cells; and

c) reintroducing said regulatory T cells to said patient to suppress an aberrant immune response.

25. A method according to claim 24 wherein said aberrant immune response is a cell-mediated autoimmune disease selected from the group consisting of Hashimoto's disease, polymyositis, disease inflammatory bowel disease, multiple sclerosis, diabetes mellitus, rheumatoid arthritis, and scleroderma.

26. A method for treating an autoimmune disorder in a patient comprising:

a) removing peripheral blood mononuclear cells (PBMC) from said patient;

b) treating said cells with a regulatory composition to induce said cells to produce immunosuppressive levels of TGF-β; and

c) reintroducing said cells to said patient to suppress aberrant immune responses.

27. A method according to claim 24 or 26 wherein said PBMCs comprise CD4+ T cells and said regulatory composition comprises TGF-β

28. A method according to claim 24 or 26 wherein said PBMCs comprise CD8+ T cells and said regulatory composition comprises TGF-β

29. A method according to claim 24 or 26 wherein said PBMCs comprise CD4+ T cells and CD8+ T cells and said regulatory composition comprises TGF-β.

30. A method according to claim 24 or 26 wherein said PBMCs comprise CD4+ T cells and said regulatory composition comprises TGF-β and IL-2.

31. A method according to claim 24 or 26 wherein said PBMCs comprise CD8+ T cells and said regulatory composition comprises TGF-β and IL-2.

32. A method according to claim 24 or 26 wherein said PBMCs comprise CD4+ T cells and CD8+ T cells and said regulatory composition comprises TGF-β and Il-2.

33. A method according to claim 24 or 26 wherein said PBMCs comprise CD4+ T cells and said regulatory composition comprises a mixture of TGF-β and anti-CD2.

34. A method according to claim 24 or 26 wherein said PBMCs comprise CD8+ T cells and said regulatory composition comprises a mixture of TGF-β and anti-CD2.

35. A method according to claim 24 or 26 wherein said PBMCs comprise CD4+ T cells and CD8+ T cells and said regulatory composition comprises a mixture of TGF-β and anti-CD2.

36. A method according to claim 24 or 26 wherein said PBMCs comprise CD4+ T cells and said regulatory composition comprises a mixture of TGF-β, IL-2 and anti-CD2.

37. A method according to claim 24 or 26 wherein said PBMCs comprise CD8+ T cells and said regulatory composition comprises a mixture of TGF-β, IL-2 and anti-CD2.

38. A method according to claim 24 or 26 wherein said PBMCs comprise CD4+ T cells and CD8+ T cells and said regulatory composition comprises a mixture of TGF-β, IL-2 and anti-CD2.

39. A method according to claim 24 or 26 wherein said PBMCs comprise CD4+ T cells and said regulatory composition comprises a mixture of TGF-β and anti-CD3.

40. A method according to claim 24 or 26 wherein said PBMCs comprise CD8+ T cells and said regulatory composition comprises a mixture of TGF-β and anti-CD3.

41. A method according to claim 24 or 26 wherein said PBMCs comprise CD4+ T cells and CD8+ T cells and said regulatory composition comprises a mixture of TGF-β and anti-CD3.

42. A method according to claim 24 or 26 wherein said PBMCs comprise CD4+ T cells and said regulatory composition comprises a mixture of TGF-β, IL-2 and anti-CD3.

43. A method according to claim 24 or 26 wherein said PBMCs comprise CD8+ T cells and said regulatory composition comprises a mixture of TGF-β, IL-2 and anti-CD3.

44. A method according to claim 24 or 26 wherein said PBMCs comprise CD4+ T cells and CD8+ T cells and said regulatory composition comprises a mixture of TGF-β, IL-2 and anti-CD3.

45. A method according to claim 24 or 26 wherein said PBMCs comprise TandK cells and said regulatory composition comprises TGF-β

46. A method according to claim 24 or 26 wherein said PBMCs comprise TandK cells and said regulatory composition comprises TGF-β and IL-2.

47. A method according to claim 24 or 26 wherein said PBMCs comprise TandK cells and said regulatory composition comprises TGF-β, IL-2 and anti-CD2.

48. A method according to claim 24 or 26 wherein said PBMCs comprise TandK cells and said regulatory composition comprises TGF-β, IL-2 and anti-CD3.

49. A method according to claim 26 wherein said wherein said aberrant immune response is an antibody mediated disease selected from the group consisting of pemphigus vulgaris, myasthenia gravis, hemolytic anemia, thrombocytopenia purpura, Grave's disease, dermatomyositis and Sjogren's disease.—

REMARKS

Claim 1 has been cancelled. Claims 24-49 are newly added. Support for new claim 24 is found in the specification at page 10, lines 13-20. Support for new claim 25 is found in the specification at page 11, lines 11-19. Support for new claim 26 is found in the specification at

page 10, lines 10-24. Support for new claims 27-29 is found in the specification at page 13, lines 1-2 and lines 34-35. Support for new claims 30-32 is found in the specification at page 13, lines 1-2 and lines 30-31. Support for new claims 33-44 is found in the specification at page 13, lines 1-2 and lines 27-30 and at page 15, lines 14-36. Support for new claim 45 is found in the specification at page 15, lines 1-3 and at page 13, lines 34-35. Support for new claim 46 is found at page 15, lines 1-3 and at page 13, lines 30-31. Support for new claims 47 and 48 is found at page 15, lines 1-3 and at page 13, lines 27-30. Support for new claim 49 is found at page 10, lines 35-37.

Attached hereto is a marked-up version of the changes made to the claims by the "Preliminary Amendment". The attached page is captioned "**Version with markings to show changes made.**"

The Commissioner is authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 06-1300 (Our Order No. 469443-00004/A-67279-5/RFT/RMS/RMK). Please direct any calls in connection with this application to the undersigned at (415) 781-1989.

Dated: 8/2/02

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Specification:

The paragraph beginning at line 3 of page 1 has been amended as follows:

This application is a continuing application of United States Serial No. 09/564,436, filed May 4, 20000, now U.S. Patent No. 6,358,506, which is a continuing application of 09/187,771, filed November 5, 1998, now U.S. Patent No. 6,228,359, and claims the benefit of the filing dates of United States Serial No. 60/132,616, filed May 5, 1999 and 60/064,507, filed November 5, 1997.

In the Claims:

Claim 1 has been cancelled.